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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/693,663	10/24/2003	Gene DiPoto	ENDIUS.033A	9623
20995 7590 05/22/2007 KNOBBE MARTENS OLSON & BEAR LLP 2040 MAIN STREET FOURTEENTH FLOOR IRVINE, CA 92614			EXAMINER SWIGER III, JAMES L	
			ART UNIT 3733	PAPER NUMBER
			NOTIFICATION DATE 05/22/2007	DELIVERY MODE ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary

Application No.

10/693,663

Applicant(s)

GENE DIPOTO

Examiner

James L. Swiger

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 February 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-32 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-32 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 4/5/2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-4, 6-12, 14-18, and 23-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Davison (US Patent 6,530,926) in view of Cornwall et al. (US Patent 6,485,518).

Davison discloses a method of securing vertebrae including the steps of inserting in a patient an access device (see Fig. 5, item 10, and Col. 2, lines 58-63), where the access device has a first and second configuration (see Col. 3, lines 3-39) that has an enlarged cross sectional area (see Fig. 1), and wherein through the access device, a fastener can be inserted to fasten vertebrae. The device is actuated from the first to second position using the expansion tool (112) and manual force and wherein the second position is considered substantially perpendicular to the spine of the patient. Further Davison discloses a method wherein the method is generally a posterior (see Fig. 5) or posterolateral approach (See Col. 12, lines 44-48), a method that has a boring tool to yield access to the vertebrae (note Davidson refers to the action of creating holes as drilling, but is regarded as a step capable of "boring" holes in preparation for the

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vertebral fasteners), preventing movement of the first vertebra in relation to the second via two fixation elements (650) into the cannula (see Col. 13, lines 18-22), wherein the same access device may be used for the second fastener.

Davison discloses the claimed method except for the step of delivering a fastener(s) through a first vertebra and into a second vertebra while providing transfacet fixation keeping the vertebrae from moving relative to one another and also wherein the second vertebra is considered adjacent in the working space. Cornwall et al. disclose an intervertebral support and fusion system that allows for transfacet fixation using a fastener (30a and 30b) through one vertebrae to another and where other vertebrae may be adjacent to the surgical site. See also Cols. 1 and 2. It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the device and perform the method of Davison having at least the step of delivering a fastener(s) through a first vertebra and into a second vertebra while providing transfacet fixation keeping the vertebrae from moving relative to one another and also wherein the second vertebra is considered adjacent in the working space in view of Cornwall et al. to better use the device to secure vertebrae.

Claims 5 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Davison '926 and Cornwall et al. '518 as applied to claims 1 and 8, respectively above, and further in view of Neubardt (US Patent 5,196,015). The combination of Davison '926 and Cornwall et al. '518 disclose the claimed method except for the step of scoring the surgical location prior to delivering the fastener through the bone. Neubardt discloses an indirect scoring of the area that is performed

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by placing the tool to the area and verifying the mark of the tool tip by indicia located on the tool shaft. (Col. 5, lines 10-16). In this way the location is marked before the fastener or securing device is delivered. It would have been obvious to one having ordinary skill in the art at the time the invention was made to incorporate into the method of the combination of Davison '926 and Cornwall et al. '518 with the step of scoring and marking the area of interest for securing the fasteners in view of Neubardt to provide accurate fixation in a minimal access procedure.

Claims 19-20 and 21-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Davison '926 and Cornwall et al. '518. The combination of Davison '926 and Cornwall et al. '518 discloses the claimed invention except for a "generally perpendicular angle being between 10 and 45 degrees, or at least less than 60." It would have been obvious to one having ordinary skill in the art at the time the invention was made to make a range of angle being between 10 and 45 degrees, or at least less than 60, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art, especially for access the spine posteriorly through a device. In re Boesch, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

Response to Arguments

Applicant's arguments filed 2/20/2007 have been fully considered but they are not persuasive. Davison discloses at least the steps of inserting fixation devices through an access device that may be actuated into in different planes with multiple cross section areas. Cornwall discloses a method that is intended to fix bones relative to each

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other, and more particularly two vertebrae that are considered to be trans-facet fixated. This interpretation is from the concept of the screw or fixation device goes through a first vertebrae and into a second one (see fig. 2 in Cornwall). To perform this procedure, access to the spinal area would have been required, and regardless of triangulation, Cornwall would ultimately fix two vertebrae relative to one another. For at least these reasons, the current rejections remain.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James L. Swiger whose telephone number is 571-272-5557. The examiner can normally be reached on Monday through Friday, 9:00am to 5:30pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

 5/14/09

JLS


EDUARDO C. ROBERT
SUPERVISORY PATENT EXAMINER